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| 24280 7590 01/03/2011 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110 | | | | |
| EXAMINER | | | | |
| DAVIS, RUTH A | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1651 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 01/03/2011 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/587,960

Applicant(s)

NADEAU ET AL.

Examiner

Ruth A. Davis

Art Unit

1651

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 16-30, 38-39 is/are pending in the application.
- 4a) Of the above claim(s) 38 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 and 16-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/10
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment, response and IDS filed on October 15, 2010 have been received and entered into the case. Claims 38 - 39 are added; claims 14, 16 - 30 and 38 - 39 are pending. All arguments have been fully considered.

Election/Restrictions

Newly submitted claims 38 – 39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: other materially different compositions may be used to promote growth of animals such as vitamins and probiotics.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38 – 39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Rejections under 35 U.S.C. 112, first paragraph, are withdrawn due to applicant's response.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. Claims 14 and 16 – 30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Olshenitsky et al. (US 6511661).

Olshenitsky teaches methods for promoting weight gain (or growth) in an animal (col.4 line 15-23) comprising administering a non-pathogenic *E. coli* (abstract) in amounts to effect weight gain, or animal growth. The composition is fed orally as a feed (col.4 line 15-23) or in a water carrier (examples) to post weaning animals such as day old calves, pigs and chickens (examples).

Olshenitsky does not teach the method wherein the carrier is milk; the claimed amounts of bacteria; the specifically claimed and deposited bacteria; or wherein the animal is a weaning mouse. However, Olshenitsky clearly teaches the method is effective for feedstuff in mammals and avian species (examples). Specifically, Olshenitsky provides examples in treating various animals at various ages and sizes, with varying amounts of bacterial cells being administered, and in various carriers based on the treated animal (see examples). Thus, in following the teachings of Olshenitsky, one of ordinary skill in the art would have been motivated to optimize the carrier, amounts of bacteria, strains of bacteria and receiving animal as a matter of routine practice and experimentation, based on the treated animal and size thereof, with a reasonable expectation for successfully promoting growth of the animal.

Response to Arguments

Applicant argues that the reference does not teach the F4+, pig specific non pathogenic E. coli and that the composition in the prior art also requires additional components.

However, these arguments fail to persuade because the reference clearly teaches a formulation effective to enhance animal weight gain (col.4 line 21-22) wherein the formulation includes a non pathogenic E. coli. As stated in the rejection above, although the reference does not teach the claimed strain, the reference clearly teaches administering non pathogenic E. coli to enhance animal growth. At the time of the claimed invention, in following the teachings of the cited reference, it would have been obvious to one of ordinary skill in the art to administer any strain of nonpathogenic E. coli with a reasonable expectation for successfully enhancing animal growth. Particularly absent evidence of an unexpected advantage or result with the claimed

strain. Regarding the reference composition including additional components, it is noted that the claims recite open ended language, thereby not excluding additional components. Thus the argument is not commensurate in scope with the claims.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner, Art Unit 1651